

Curriculum Vitae

Personal information **Viviana Giannuzzi**

Work experience

START DATE: 31/07/2010

END DATE: present

POSITION HELD: Head of the Research Department.

EMPLOYER'S NAME: Fondazione per la Ricerca Farmacologica Gianni Benzi onlus (ITALY)

MAIN ACTIVITIES IN THE POSITION: Senior scientist, Senior regulatory manager: European medicine regulatory procedures, ethical/regulatory support to the preparation of documents for clinical studies (protocol, material for the informed consent and assent process., etc). Researcher and leader of ethics and regulatory activities/work packages in EU projects. Project manager of EuOrphan, project writer for grant applications, networking.

START DATE: April 2008

END DATE: July 2010

POSITION HELD: Scientific Secretary of Ethics Committee

EMPLOYER'S NAME: ASL Lecce (ITALY)

MAIN ACTIVITIES IN THE POSITION: Support to the evaluation of interventional and non-interventional studies and other applications, and the application of current international and national provisions; National Monitoring Centre for Clinical Trials management and data entry.

START DATE: November 2006

END DATE: January 2009

POSITION HELD: Postdoctoral fellow

EMPLOYER'S NAME: University of Bari (ITALY)

MAIN ACTIVITIES IN THE POSITION: Non-clinical and basic research activity: cytofluorimetric evaluation of calcium homeostasis and calcium channels activity in physiological and pathological situations including rare diseases (ageing, simulated microgravity, muscular Duchenne dystrophy), in vitro and in vivo therapeutic and toxic effects of drugs; preparation of native muscular fibres from mechanical dissection of rodent muscles; fura-2 imaging technique; Education and training activities in pharmacology, pharmacotherapy and toxicology, drug research, regulatory sciences, paediatric medicines and research.

START DATE: February 2006

END DATE: June 2006

POSITION HELD: Visiting PhD student

EMPLOYER'S NAME: Université Pierre et Marie Curie & CNRS – Paris (FRANCE)

MAIN ACTIVITIES IN THE POSITION: Pharmacological characterization of native CLC-K renal chloride channels; dissection of rodent kidneys and tubules; patch-clamp technique.

Education and training

1. Post-graduate II-level Master

- START DATE: December 2008

- END DATE: December 2009

- DEGREE/QUALIFICATION OBTAINED: **Post-graduate II-level Master in Clinical Research of Medicines**

- INSTITUTION: University of Pisa, ITALY

- SUBJECTS/SKILLS COVERED: Clinical trial methodology, protocol design, enrolment of patients, efficacy and safety evaluation of investigational treatment, rules and procedures on clinical research, role of investigators, patients/subjects information, ethical issues, pharmacogenetic studies, collection of study data, role and tasks of Ethics Committees.

2. PhD

- START DATE: October 2003

- END DATE: October 20036

- DEGREE/QUALIFICATION OBTAINED: **PhD in Cellular Biochemistry and Cellular Pharmacology**

- INSTITUTION: University of Bari, ITALY

- SUBJECTS/SKILLS COVERED: Non clinical research on skeletal muscle calcium homeostasis. Thesis: Muscular disuse and calcium homeostasis: effects of ageing and simulated microgravity on rat slow-twitch and fast-twitch muscle and pharmacological interventions.

3. Second-level Degree in Pharmacy

- START DATE (month, year): August 1998

- END DATE (month, year): July 2023

- DEGREE/QUALIFICATION OBTAINED:

- INSTITUTION: University of Bari, ITALY

- SUBJECTS/SKILLS COVERED: Effects of a Growth Hormone secretagogue on calcium homeostasis in native rat muscle fibres.

Additional information

Publications

1. Frayse B., Desaphy J-F., Rolland J.F., Pierro S. Liantonio A., Giannuzzi V., Camerino C., Didonna M.P., Cocchi D., De Luca A., Conte Camerino D.: Fiber type-related changes in rat skeletal muscle calcium homeostasis during aging and restoration by growth hormone. *Neurobiology of Disease* 2006; 21(2): 372-80 (ISSN: 0969-9961 (Print); 1095-953X (Electronic)).
2. Liantonio A., Giannuzzi V., Piccolo A., Babini E., Pusch M., Conte Camerino D. Niflumic acid inhibits chloride conductance of rat skeletal muscle by directly inhibiting the CLC-1 channel and by increasing intracellular calcium. *British Journal of Pharmacology* 2007; 150(2): 235-47 (ISSN: 0007-1188 (Print); 1476-5381 (Electronic)).
3. Liantonio A., Giannuzzi V., Cippone V., Camerino G.M., Pierro S., Conte Camerino D.: Fluvastatin and atorvastatin affect calcium homeostasis of rat skeletal muscle fibers in vivo and in vitro by impairing the sarcoplasmic reticulum/mitochondria Ca²⁺-release system. *J. Pharmacol. Exp. Ther.* 2007; 321(2): 626-349 (ISSN: 0022-3565 (Print); 1521-0103 (Electronic)).
4. De Luca A, Nico B, Rolland JF, Cozzoli A, Burdi R, Mangieri D, Giannuzzi V., Liantonio A, Cippone V, De Bellis M, Nicchia GP, Camerino GM, Frigeri A, Svelto M, Camerino DC. Gentamicin treatment in exercised mdx mice: Identification of dystrophin-sensitive pathways and evaluation of efficacy in work-loaded dystrophic muscle. *Neurobiol Dis.* 2008 Nov;32(2):243-53. doi: 10.1016/j.nbd.2008.07.009.
5. Burdi R, Rolland JF, Frayse B, Litvinova K, Cozzoli A, Giannuzzi V., Liantonio A, Camerino GM, Sblendorio V, Capogrosso RF, Palmieri B, Andreetta F, Confalonieri P, De Benedictis L, Montagnani M, De Luca A. Multiple pathological events in exercised dystrophic mdx mice are targeted by pentoxifylline: outcome of a large array of in vivo and ex vivo tests. *J Appl Physiol.* 2009; 106: 1311-1324 (ISSN: 0021-8987).
6. A. Liantonio, S. Pierro, C. Digennaro, V. Giannuzzi, G. Gramegna, J-F. Desaphy, D. Conte Camerino The hindlimb unloading model of microgravity differently affects skeletal muscle properties of young and adult mice. *Basic Applied Myology* 19 (2&3): 107-112, 2009 (ISSN: 1120-9992).
7. Desaphy JF, Pierro S, Liantonio A, Giannuzzi V., Digennaro C, Dinardo MM, Camerino GM, Ricciuti P, Brocca L, Pellegrino MA, Bottinelli R, Camerino DC. Antioxidant treatment of hindlimb-unloaded mouse counteracts fiber type transition but not atrophy of disused muscles. *Pharmacol Res.* 2010 Jun;61(6):553-63. doi: 10.1016/j.phrs.2010.01.012.
8. Liantonio A, Gramegna G, Carbonara G, Sblendorio VT, Pierro S, Frayse B, Giannuzzi V., Rizzi L, Torsello A, Camerino DC. Growth hormone secretagogues exert differential effects on skeletal muscle calcium homeostasis in male rats depending on the peptidyl/nonpeptidyl structure. *Endocrinology.* 2013 Oct;154(10):3764-75. doi: 10.1210/en.2013-1334.
9. Cassis L, Cortès-Saladelfont E, Molero-Luis M, Yubero D, González MJ, Ormazábal A, Fons C, Jou C, Sierra C, Castejon Ponce E, Ramos F, Armstrong J, O'Callaghan MM, Casado M, Montero R, Meavilla-Olivas S, Artuch R, Barić I, Bartoloni F, Bellettato CM, Bonifazi F, Ceci A, Cvitanović-Šojat L, Dali CI, D'Avanzo F, Fumic K, Giannuzzi V, Lampe C, Scarpa M, García-Cazorla Á. Review and evaluation of the methodological quality of the existing guidelines and recommendations for inherited neurometabolic disorders. *Orphanet J Rare Dis.* 2015 Dec 30;10:164. doi: 10.1186/s13023-015-0376-9. Erratum in: *Orphanet J Rare Dis.* 2016 Nov 3;11(1):147.
10. Ruggieri L, Giannuzzi V, Baiardi P, Bonifazi F, Davies EH, Giaquinto C, Bonifazi D, Felisi M, Chiron C, Pressler R, Rabe H, Whitaker MJ, Neubert A, Jacqz-Aigrain E, Eichler I, Turner MA, Ceci A; GRiP Consortium. Successful private-public funding of paediatric medicines research: lessons from the EU programme to fund research into off-patent medicines. *Eur J Pediatr.* 2015 Apr;174(4):481-91. doi: 10.1007/s00431-014-2398-z.
11. Giannuzzi V, Altavilla A, Ruggieri L, Ceci A. Clinical Trial Application in Europe: What Will Change with the New Regulation? *Sci Eng Ethics.* 2016 Apr;22(2):451-66. doi: 10.1007/s11948-015-9662-0.
12. Conte R, Ruggieri L, Gambino A, Bartoloni F, Baiardi P, Bonifazi D, Bonifazi F, Felisi M, Giannuzzi V, Padula R, Pepe A, Putti MC, Del Vecchio GC, Maggio A, Filosa A, Iacono A, Mangiarini L, Ceci A. The Italian multiregional thalassemia registry: Centers characteristics, services, and patients' population. *Hematology.* 2016 Aug; 21(7):415-24. doi: 10.1080/10245332.2015.1101971.
13. Giannuzzi V, Devlieger H, Margari L, Odland VL, Ragab L, Bellettato CM, D'Avanzo F, Lampe C, Cassis L, Cortès-Saladelfont E, Cazorla AG, Barić I, Cvitanović-Šojat L, Fumic K, Dali CI, Bartoloni F, Bonifazi F, Scarpa M, Ceci A. The ethical framework for performing research with rare inherited neurometabolic disease patients. *Eur J Pediatr.* 2017 Mar; 176(3):395-405. doi: 10.1007/s00431-017-2852-9.
14. Giannuzzi V, Conte R, Landi A, Ottomano SA, Bonifazi D, Baiardi P, Bonifazi F, Ceci A. Orphan medicinal products in Europe and United States to cover needs of patients with rare diseases: an increased common effort is to be foreseen. *Orphanet J Rare Dis.* 2017 Apr 3;12(1):64. doi: 10.1186/s13023-017-0617-1.
15. Neubert A, Baarslag MA, Dijk MV, Rosmalen JV, Standing JF, Sheng Y, Rascher W, Roberts D, Winslade J, Rawcliffe L, Hanning SM, Metsvaht T, Giannuzzi V, Larsson P, Pokorná P, Simonetti A, Tibboel D; CLOSED Consortium. The CLOSED trial; CLONidine compared with midazolam for SEDation of paediatric patients in the intensive care unit: study protocol for a multicentre randomised controlled trial. *BMJ Open.* 2017 Jun 21;7(6):e016031. doi: 10.1136/bmjopen-2017-016031. Erratum in: *BMJ Open.* 2017 Nov 8;7(11):e016031corr1.

16. Giannuzzi V, Landi A, Bosone E, et al Failures to further developing orphan medicinal products after designation granted in Europe: an analysis of marketing authorisation failures and abandoned drugs *BMJ Open* 2017;7:e017358. doi: 10.1136/bmjopen-2017-017358.
17. Bonifazi F, Conte R, Baiardi P, Bonifazi D, Felisi M, Giordano P, Giannuzzi V, Iacono A, Padula R, Pepe A, Caterina Putti M, Ruggieri L, Carlo Del Vecchio G, Filosa A, Maggio A, Ceci A; HTA-THAL Multiregional Registry. Pattern of complications and burden of disease in patients affected by beta thalassemia major. *Curr Med Res Opin.* 2017 Aug;33(8):1525-1533. doi: 10.1080/03007995.2017.1326890.
18. Giannuzzi V, Landi A, Bartoloni F, Ceci A. A Review on Impact of General Data Protection Regulation on Clinical Studies and Informed Consent. *J Clin Res Bioeth* 2018; 9(3):327. doi: 10.4172/2155-9627.1000327.
19. Ceci A, Conte R, Didio A, Bonifazi D, Felisi M, Giannuzzi V, Bonifazi F. An overview of the efficacy and safety of deferiprone in paediatric patients with congenital haemoglobinopathies and chronic iron overload. *Expert Opinion on Orphan Drugs.* 2019; 7:4, 181-197. doi: 10.1080/21678707.2019.1613977.
20. Landi A, Thompson M, Giannuzzi V, Bonifazi F, Labastida I, Bonino da Silva Santos L.O, Roos M. The "A" of FAIR – As open as possible, as closed as necessary. *Data Intelligence.* 2(2020), 47–55. Doi: 10.1162/dint_a_00027.
21. Bonifazi F, Volpe E, Digregorio G, Giannuzzi V, Ceci A. Machine Learning Systems Applied to Health Data and System. *Eur J Health Law.* 2020 May 19;27(3):242-258. doi: 10.1163/15718093-BJA10009. PMID: 33652397.
22. Toma M, Felisi M, Bonifazi D, Bonifazi F, Giannuzzi V, Reggiardo G, de Wildt S, Ceci A; TEDDY European Network of Excellence for Paediatric Research. Paediatric Medicines in Europe: The Paediatric Regulation-Is It Time for Reform? *Front Med (Lausanne).* 2021 Feb 2;8:593281. doi: 10.3389/fmed.2021.593281. PMID: 33604345; PMCID: PMC7884470.
23. Kountouris P, Stephanou C, Archer N, Bonifazi F, Giannuzzi V, Kuo KHM, Maggio A, Makani J, Mañú-Pereira MDM, Michailidou K, Nkya S, Nnodu OE, Trompeter S, Tshililo L, Wonkam A, Zilfalil BA, Inusa BPD, Kleanthous M; on behalf of the International Hemoglobinopathy Research Network (INHERENT). The International Hemoglobinopathy Research Network (INHERENT): An international initiative to study the role of genetic modifiers in hemoglobinopathies. *Am J Hematol.* 2021 Nov 1;96(11):E416-E420.
24. Lepola P, Kindred M, Giannuzzi V, Glosli H, Dehlinger-Kremer M, Dalrymple H, Neubauer D, Boylan GB, Conway J, Dewhurst J, Hoffman D. Informed consent and assent guide for paediatric clinical trials in Europe. *Arch Dis Child.* 2021 Dec 1;archdischild-2021-322798. doi: 10.1136/archdischild-2021-322798. Epub ahead of print. PMID: 34853000.
25. Giannuzzi V, Felisi M, Bonifazi D, Devlieger H, Papanikolaou G, Ragab L, Fattoum S, Tempesta B, Reggiardo G, Ceci A. Ethical and procedural issues for applying researcher-driven multi-national paediatric clinical trials in and outside the European Union: the challenging experience of the DEEP project. *BMC Med Ethics.* 2021 Apr 29;22(1):49. doi: 10.1186/s12910-021-00618-2. PMID: 33926431; PMCID: PMC8086274.
26. Fernández-Luis S, Lain MG, Serna-Pascual M, Domínguez-Rodríguez S, Kuhn L, Liberty A, Barnabas S, Lopez-Varela E, Otworld K, Danaviah S, Nastouli E, Palma P, Cotugno N, Spyer M, Giannuzzi V, Giaquinto C, Violari A, Cotton MF, Nhampossa T, Klein N, Ramsagar N, van Rensburg AJ, Behuhuma O, Vaz P, Maiga AI, Oletto A, Naniche D, Rossi P, Rojo P, Tagarro A; EPIICAL Consortium. Optimizing the World Health Organization algorithm for HIV vertical transmission risk assessment by adding maternal self-reported antiretroviral therapy adherence. *BMC Public Health.* 2022 Jul 8;22(1):1312. doi: 10.1186/s12889-022-13543-9. PMID: 35804333; PMCID: PMC9264598.
27. Giannuzzi V, Stoyanova-Beninska V, Hivert V. Editorial: The use of real world data for regulatory purposes in the rare diseases setting. *Front Pharmacol.* 2022 Nov 24;13:1089033. doi: 10.3389/fphar.2022.1089033. PMID: 36506540; PMCID: PMC9730868.
28. Ceci A, Conte R, Didio A, Landi A, Ruggieri L, Giannuzzi V, Bonifazi F. Target therapy for high-risk neuroblastoma treatment: integration of regulatory and scientific tools is needed. *Front Med (Lausanne).* 2023 Jul 14;10:1113460. doi: 10.3389/fmed.2023.1113460. PMID: 37521350; PMCID: PMC10377668.
29. Giannuzzi V, Ruggieri L, Conte R, Manfredi C, Felisi M, Kubiak C, Matei M, Malik S, Demotes J, Ceci A, Bonifazi D. PedCRIN tool for the biosamples management in pediatric clinical trials. *Clin Transl Sci.* 2023 Feb 9. doi: 10.1111/cts.13489. Epub ahead of print. PMID: 36757003.
30. Kerpel-Fronius S, Stoyanova-Beninska V, Giannuzzi V, Sun Z. Editorial: Reviews in: regulatory science. *Front. Med.,* 16 May 2023 Sec. Regulatory Science. Volume 10 - 2023. <https://doi.org/10.3389/fmed.2023.1206753>.
31. Mastrolorito F, Togo MV, Gambacorta N, Trisciuzzi D, Giannuzzi V, Bonifazi F, Liantonio A, Imbrici P, De Luca A, Altomare CD, Ciriaco F, Amoroso N, Nicolotti O. TISBE: A Public Web Platform for the Consensus-Based Explainable Prediction of Developmental Toxicity. *Chem Res Toxicol.* 2024 Jan 10. doi: 10.1021/acs.chemrestox.3c00310.
32. Giannuzzi V, Bertolani A, Torretta S, Reggiardo G, Toich E, Bonifazi D, Ceci A. Innovative research methodologies in the EU regulatory framework: an analysis of EMA qualification procedures from a pediatric perspective. *Front Med (Lausanne).* 2024 Mar 28;11:1369547. doi: 10.3389/fmed.2024.1369547.
33. Landi A, Mimouni Y, Giannuzzi V, Schaefer F, Altavilla A, Gibson S, Julkowska D. The creation of an adaptable informed consent form for research purposes to overcome national and institutional bottlenecks in ethics review: experience from rare disease registries. *Front Med (Lausanne).* 2024 Apr 17;11:1384026. doi: 10.3389/fmed.2024.1384026.
34. Tagarro A, Domínguez-Rodríguez S, Cotton M, Otworld K, Klein N, Lain MG, Nhampossa T, Maiga AI, Barnabas S, Vaz P, Violari A, Fernández-Luis S, Behuhuma O, Sylla M, López-Varela E, Naniche D, Janse-Van-Rensburg A, Liberty A, Ramsagar N, Smit T, Makhari S, Ismael N, Giaquinto C, Rossi P, Kuhn L, Palma P, Spyer M, Lichterfeld M, Nastouli E, Giannuzzi V, Ballesteros A, Cotugno N, Morrocchi E, Oletto A, Traoré FT, Dobbels E, Akhalwaya Y, Ording-Jespersen G, Foster C, Rabie H, Amuge P, Brehin C, Pahwa S, Coulibaly YA, Rojo P; EPIICAL Consortium. High mortality following early initiation of antiretroviral therapy in infants living with HIV from three African countries. *EClinicalMedicine.* 2024 May 23;73:102648. doi: 10.1016/j.eclim.2024.102648.
35. Wang S, Giannuzzi V. Paediatric formulations-part of the repurposing concept? *Front Med (Lausanne).* 2024 Sep 16;11:1456247. doi: 10.3389/fmed.2024.1456247.
36. Landi A, D'Ambrosio F, Faggion S, Rocchi F, Paganin C, Lain MG, Ceci A, Giannuzzi V; EPIICAL Consortium. Sharing Data and Transferring Samples Within Pediatric Clinical Studies: How to Overcome Challenges and Make Them a Science Opportunity. *Healthcare (Basel).* 2024 Dec 6;12(23):2473. doi: 10.3390/healthcare12232473.
37. Ruggieri L, Torretta S, Giannuzzi V, Natale A, Felisi M, Ceci A, Bonifazi F. Effects of the Paediatric Regulation funding on the development of off-patent medicines in children. *Front Med (Lausanne).* 2025 Jan 30;11:1473862. doi: 10.3389/fmed.2024.1473862.
38. Declerck J, Lee J, Sen A, Palmeri A, Oostenbrink R, Giannuzzi V, Woodworth S, Malik S, Mahler F, Aurich B, Leary R, Kalra D, Straub V. The Potential to Leverage Real-World Data for Pediatric Clinical Trials: A Proof-of-Concept Study. *J Med Internet Res.* 2025 May 30;27:e72573. doi: 10.2196/72573. PMID: 40446289; PMCID: PMC12166320.

39. Didio A, Giannuzzi V, Archer N, Gani E, Sblano S, Peprah E, Kountouris P, Bonifazi F; International Hemoglobinopathy Research Network (INHERENT). Ethical and regulatory requirements for conducting researcher-driven large-scale multinational genetic haematological studies: the INHERENT experience. Health Res Policy Syst. 2025 Aug 5;23(1):101. doi: 10.1186/s12961-025-01375-z.

40. Reggiardo G, Natale A, Santoro N, Giannuzzi V, Pansieri C, Felisi M, Bonifazi D, Ceci A. Scientific and regulatory progress in advancing paediatric oncology drug development in the EU and in the US. Front Med (Lausanne). 2025 Sep 26;12:1642279. doi: 10.3389/fmed.2025.1642279.

Projects

[31/08/2009 – 30/07/2010]

Task-force in Europe for Drug Development for the Young (TEDDY) Scientific co-coordinator of the e-learning platform FP6-LIFESCIHEALTH (Grant agreement ID: 5216; DOI: 10.2165/0148581-200911010-00008).

Link: <https://cordis.europa.eu/project/id/5216>

[31/01/2010 – 31/12/2013]

Antibiotic Resistance and Prescribing in European Children (ARPEC) Education and training activities; Regulatory and ethical support on data protection issues (2009 11 01, Health Programme).

Link: https://webgate.ec.europa.eu/chafea_pdb/health/projects/20091101/summary

[31/12/2010 – 30/10/2016]

Deferiprone Evaluation in Paediatrics (DEEP) Coordinating the application of multi-national paediatric clinical studies; ethical and regulatory advice (EU FP7 - HEALTH-F4-2010-261483; Grant Agreement 261483).

Link: <https://cordis.europa.eu/project/id/261483/it>; <https://deepproject.cvbf.net/index.html>

[31/12/2010 – 29/06/2017]

Global Research in Paediatrics (GRiP) e-learning on ethical and regulatory aspects of paediatric research (EU FP7 Network of Excellence - HEALTH-F5-2010-261060; Grant agreement: 261060).

Link: <https://cordis.europa.eu/project/id/261060>.

[31/03/2013 – 30/09/2015]

Inherited NeuRoMetabolic Diseases INFORMATION NETWORK (InNerMeD-INETWORK) Leader of the Work Package setting up the platform; researcher, ethical and regulatory expert within the work package on methodologies. (2012 12 12, Second Health Programme 2008-2013).

Link: https://webgate.ec.europa.eu/chafea_pdb/health/projects/20121212/summary

[30/06/2013 – 29/06/2017]

GAbapentin in Paediatric Pain (GAPP) Ethical and regulatory advice on nonclinical and paediatric clinical studies, support to the coordination of the multi-national clinical studies, ICH-Good Clinical Practice (GCP) Training Course for investigators (602962 - FP7-HEALTH-2013-INNOVATION-1).

Link: <https://cordis.europa.eu/project/id/602962>

[30/11/2013 – 29/11/2018]

Clonidine for Sedation of Paediatric Patients in the Intensive Care Unit (CloSed) Ethical and regulatory advice and support to the coordination of the paediatric multi-national clinical study preparation and application (602453 - FP7-HEALTH-2013-INNOVATION-1).

Link: <https://cordis.europa.eu/project/id/602453>

[31/12/2015 – 30/12/2018]

Small Medicines Advanced Research Training (SMART) on-line and face to face training on methodological, ethical and regulatory issues of paediatric trials (692327 - H2020-TWINN-2015).

Link: <https://cordis.europa.eu/project/id/692327> DOI: 10.3030/692327

[08/02/2016 – 31/08/2024]

Early treated Perinatally HIV Infected individuals: Improving Children's Actual Life (EPIICAL) Leader of the Work Package on ethics and regulatory.

Link: <https://www.epiical.org/>

[31/12/2016 – 29/06/2021]

Paediatric Clinical Research Infrastructure Network (PedCRIN) Ethical and regulatory expert, training on the management of biosamples in paediatric clinical trials. Grant agreement: 731046; DOI: 10.3030/731046.

Link: <https://cordis.europa.eu/project/id/731046>

[31/12/2017 – 29/04/2020]

European Paediatric Translational Research Infrastructure (ID-EPTRI) Ethics Advisory Board member Grant agreement: 777554; DOI: 10.3030/777554

Link: <https://cordis.europa.eu/project/id/777554>

[01/05/2018 – Current]

connect4children (COLlaborative Network for European Clinical Trials For Children) Teacher of c4c courses on regulatory and ethical issues and training on research ethics, Ethics Committees, informed consent and assent in paediatric clinical trials; member of the Real World Data collaboration group. (Grant Agreement n. 777389, H2020-JTIIMI2-

2016-10-two-stage; 777389-IMI2-2016-10-04; DOI: 10.3030/777389).

Link: <https://cordis.europa.eu/project/id/777389>; <https://connect4children.org/>

[31/12/2018 – 31/07/2020]

African Research and Innovative Initiative for Sickle cell Education: Improving Research Capacity for Service Improvement (ARISE) Leader of Work Package on Ethics requirements (824021-H2020-MSCA-RISE-2018; Grant agreement: 824021; DOI: 10.3030/824021).

Link: <https://cordis.europa.eu/project/id/824021>; <https://www.ariseinitiative.org/>

[01/01/2019 – 31/08/2024]

European Joint Programme on Rare Diseases (EJP RD) Principal investigator for Fondazione Benzi to lead the Work Package on ethics, regulatory and IPR. (825575- SC1-BHC-04-2018)

Link: <https://cordis.europa.eu/project/id/825575>

[28/06/2021 – 16/11/2022]

Study supporting the impact assessment of the revision of the EU legislation on medicines for children and rare diseases Team member in the "Study supporting the impact assessment of the revision of the EU legislation on medicines for children and rare diseases" (rif.to Specific contract No SANTE - 2020-B5-079 – SI2.844996, under the framework contract No SANTE/2016/A1/039 – Lot 1).

[01/01/2024 – Current]

Innovative designs, extrapolation, simulation methods and evidence-tools for rare diseases addressing regulatory needs (INVENTS) Principal investigator for TEDDY network to coordinate ethics and regulatory activities; co-leader of Work Package "Ethical, legal issues and patients' engagement in a regulatory perspective" (HORIZONHLTH-2023-IND-06 call; Grant Agreement: 101136365).

Link: <https://invents-he.eu/>; <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/how-toparticipate/>

org-details/9999999999/project/101136365/program/43108390/details

[01/01/2024 – Current]

Ecosystem for rapid adoption of modelling and simulation METHODS to address regulatory needs in the development of orphan and paediatric medicines (ERAMET) Principal investigator for Fondazione Benzi to support regulatory and methodological activities (HORIZON-HLTH-2023-IND-06 call; Grant Agreement: 101137141)

Link: <https://www.erametproject.eu/>; <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/how-toparticipate/>

[toparticipate/](#)
org-details/999999999/project/101137141/program/43108390/details
[01/07/2024 – Current]
Fostering F.A.I.R. Data and Standards in Rare Hematological Diseases (HemaFAIR) (101159589 HORIZONWIDERA-2023-ACCESS-02).
Link: <https://hemafairproject.eu/>
[01/09/2024 – Current]
European Rare Diseases Research Alliance (ERDERA) Principal investigator for Fondazione Benzi and co-Leader of Work Package 'Regulatory Support Service' and WorkStream 'Expertise'. Grant Agreement n. 101156595, HORIZONHLTH-2023-DISEASE-07
Link: <https://erdera.org/>

Memberships

EURORDIS Therapeutic Action Group (TAG);
Rete A.Ma.Re. Puglia;
Patients association APS "Bottega del sorriso";
TEDDY European Network of Excellence for Paediatric Research;
HTA-Thal Registry Scientific Committee.

Other Relevant Information

I am a patient representative